For Immediate Release

SUCCESSFUL PARASOL COLLABORATION DATA ANALYSIS OUTCOME

- Final data analysis by the PARASOL collaboration with Dimerix has been received and is generally consistent with the broader analysis of all FSGS patient data conducted by PARASOL in 2024
- A potential relationship between proteinuria at 12 months and subsequent risk of kidney failure was observed, and this potential relationship will now be the subject of discussions with the FDA on possible pathways for approval

MELBOURNE, Australia, 8 October 2025: Dimerix Limited (ASX: DXB), a biopharmaceutical company with a Phase 3 clinical asset in kidney disease, is pleased to announce that the final data analysis by the PARASOL collaboration with Dimerix has been received. This analysis of observational data from major renal registries was conducted to provide Dimerix with further rationale to support the choice of proteinuria endpoints at 104 weeks for the ACTION3 study for potential marketing approval in the US. In addition, the analysis explored the relationship between proteinuria endpoints at 12 months and the subsequent risk of kidney failure and eGFR endpoints to support a potential application for Accelerated Approval.

The PARASOL analysis used a patient population that emulated the ACTION3 clinical study population (i.e. using the major ACTION3 inclusion and exclusion criteria). Pleasingly the results of this analysis are generally consistent with the broader PARASOL analysis conducted in 2024 that supported the use of proteinuria as an endpoint for FSGS clinical trials. The results of the analysis cannot be disclosed at this time, as they are based on the analysis of the PARASOL observational data (not ACTION3 data) and are subject to commercial-in-confidence restrictions.

104 week (2-year) PARASOL data support proteinuria endpoints for proposed traditional approval pathway in US

The PARASOL collaboration analysis has further demonstrated that in adults both 1) “proteinuria percent change from baseline” (continuous variable) or 2) a “proteinuria responder analysis” may be appropriate for use as a primary endpoint at 104 weeks in the US. In April, 2025, Dimerix previously reported that FDA confirmed that suitable proteinuria primary endpoints could include either: the proportion of patients achieving a defined proteinuria reduction compared to the placebo arm after 2-years of treatment; or the percentage change in proteinuria from baseline after 2-years of treatment.

52 week (12-month) PARASOL analysis

A potential relationship between proteinuria at 12 months and subsequent risk of kidney failure was observed. This potential relationship between proteinuria-based endpoints at 12 months to support marketing approval, and the subsequent use of eGFR-based endpoints over 24 months as confirmatory data, will be the subject of further discussions with the FDA. If there is agreement on this approach from the FDA, and the planned blinded analysis (sample size-estimation) for ACTION3 confirms the statistical powering assumptions for the eGFR-based endpoints, Dimerix will consider formal assessment of these earlier endpoints for potential submission.

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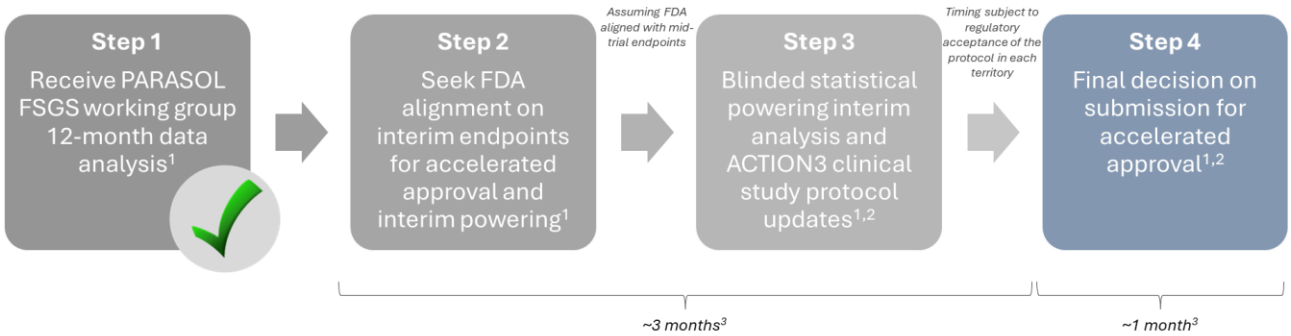
Next Steps

Dimerix and its US partner, Amicus Therapeutics (NASDAQ: FOLD), intend to seek feedback from the FDA on the new PARASOL findings in the coming months, prior to completing the planned blinded analysis of the ACTION3 data, to align on 104-week endpoints, as well as any potential accelerated approval submission.



Dimerix continues to work with its commercial partners across key territories to determine the potential for alternative approval pathways outside of the US.

> "Pleasingly, the PARASOL collaboration analysis outcome is in line with our expectations and (consistent with the initial PARASOL analysis) demonstrates a relationship between proteinuria at both the 12 month and 24 month time points and subsequent risk of kidney failure, when assessed using both responder analysis and percent change from baseline. We look forward to discussing these findings with the FDA in due course. These outcomes are a testament to the collaborative nature of the PARASOL group, and their statistical lead - Dr Abigail Smith (Associate Professor of Biostatistics and Informatics at Northwestern University). We look forward to updating the market in due course."
>
> *Dr David Fuller, Chief Medical Officer, Dimerix*

About ACTION3 FSGS Phase 3 Study

The Phase 3 study, which is titled "Angiotensin II Type 1 Receptor (AT1R) & Chemokine Receptor 2 (CCR2) Targets for Inflammatory Nephrosis", or ACTION3 for short, is a pivotal (Phase 3), multi-centre, randomised, double-blind, placebo-controlled study of the efficacy and safety of DMX-200 in patients with FSGS who are receiving a stable dose of an angiotensin II receptor blocker (ARB). Once the ARB dose is stable, patients are then randomised to receive either DMX-200 (120 mg capsule, twice daily) or placebo.

The single Phase 3 trial in FSGS patients has two interim analysis points built in that are designed to capture evidence of proteinuria and kidney function (eGFR slope) during the trial, aimed at generating sufficient evidence to support marketing approval. Further information about the study can be found on ClinicalTrials.gov (Study Identifier: NCT05183646) or Australian New Zealand Clinical Trials Registry (ANZCTR) (Study Identifier ACTRN12622000066785).

For further information, please visit our website at www.dimerix.com or contact:

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Authorised for lodgement by the Board of the Company

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About Dimerix Limited

Dimerix (ASX: DXB) is a clinical-stage biopharmaceutical company working to improve the lives of patients with inflammatory diseases, including kidney diseases. Dimerix is currently focused on developing its proprietary Phase 3 product candidate DMX-200, for Focal Segmental Glomerulosclerosis (FSGS) kidney disease, and is also developing DMX-700 for respiratory disease. DMX-200 and DMX-700 were both identified using Dimerix's proprietary assay, Receptor Heteromer Investigation Technology (Receptor-HIT), which is a scalable and globally applicable technology platform, enabling the understanding of receptor interactions to rapidly screen and identify new drug opportunities. For more information, please visit the company's website at www.dimerix.com and follow on X and LinkedIn.

About DMX-200

DMX-200 is a chemokine receptor (CCR2) antagonist administered to patients already receiving an angiotensin II type I receptor (AT1R) blocker, the standard of care treatment for hypertension and kidney disease. DMX-200 is protected by granted patents in various territories until 2032, with patent applications submitted globally that may extend patent protection to 2042, in addition to Orphan Drug Designation granted by the FDA in the United States.

About FSGS

FSGS is a rare, serious kidney disorder characterised by progressive scarring (sclerosis) in parts of the glomeruli—the kidney's filtering units. This scarring leads to proteinuria, progressive loss of kidney function, and often end-stage renal disease. FSGS is increasingly understood to have an inflammatory component, with monocyte and macrophage activation contributing to glomerular injury. In the United States, more than 40,000 people are estimated to be living with FSGS, including both adults and children.

[4] There are no therapies specifically approved for FSGS in the U.S., and disease management relies on non-specific immunosuppressive and supportive therapies. In patients with progressive or treatment-resistant FSGS, the average time from diagnosis to end-stage kidney disease can be as short as five years. Even among those who undergo kidney transplantation, disease recurrence occurs in up to 60% of cases,[5] underscoring the urgent need for new, disease-modifying treatments.

Dimerix Forward Looking Statement

This release includes forward-looking statements that are subject to risks and uncertainties. Although management believes that the expectations reflected in the forward-looking statements are reasonable at this time, Dimerix can give no assurance that these expectations will prove to be correct. Readers are cautioned not to place undue reliance on forward-looking statements. Actual results could differ materially from those anticipated. Reasons may include risks associated with drug development and manufacture, risks inherent in the regulatory processes, delays in clinical trials, results of clinical trials, contractual risks, risks associated with patent protection, future capital needs or other general risks or factors, along with those factors outlined in the most recent Dimerix Limited Annual Report.

References

1 *ASX release 28 April 2025*

2 *The potential for any unblinding and accelerated (or conditional) approval submissions, following the second interim analysis, are subject to agreement with the appropriate regulatory authorities such as the FDA in the US, and the statistical powering of the ACTION3 study, following the planned blinded analysis*

3 *Timing subject to FDA feedback and acceptance of regulatory protocol in each territory*

4 *Nephcure FSGS Facts (https://nephcure.org/)*

5 *Front. Immunol., (July 2019) | https://doi.org/10.3389/fimmu.2019.01669*